

R E M A R K S

This is in response to the Office Action that was mailed on December 6, 2004. The specification and claims are amended as required by the Examiner on pages 6-7 of the Office Action. Also, the claims are amended to facilitate understanding of the addition reactions and the substitution reactions that constitute embodiments of the present invention. No new matter is introduced by this Amendment. Entry of this Amendment - in order to place the application into condition for allowance or ***in order to reduce the issues for appeal*** - is respectfully solicited. Claims 1-3, 14-21, 23, and 24 remain pending in the application.

Objection was raised to the specification, on page 8 of the Office Action. The present amendment of the specification obviates the objection of record.

Claims 1, 3, 21, 23, and 24 were rejected under the second paragraph of 35 U.S.C. §112 as failing to define the invention properly. Office Action, pages 6-8.

Based upon the Examiner's comments at the top of page 7 of the Office Action, it appears that claims 23 and 24 are rejected only because they depend from claims 1 and 3 containing language deemed objectionable by the Examiner with respect to addition and substitution reactions and unsaturated bonds. The language in question has been removed from the claims, thereby obviating this ground of rejection and ***reducing the issues for appeal***.

Claims 1, 3, and 21 were also rejected for failure "to recite the specific reagents and product thereof". Nothing in the language of the statute requires the recitation of specific reagents or specific products in a process claim. On the contrary, the law is quite clear that the focus under the second paragraph of 35 U.S.C. §112 is on what applicants intend. "When the applicant states the meaning that the claim terms are intended to have, the claims are examined with that meaning, in order to achieve a complete exploration of the applicant's invention and its relation to the prior art." *In re Zletz*, 13 USPQ2d 1320, at 1322. The *Fressola* case, also cited by the Examiner, does not contradict this view of the law. In *Fressola*, the claim in question was directed to a system for the display of stereographic three-dimensional images of celestial objects "as disclosed in the specification and drawings herein". The claims in the present application do not refer to the specification or drawings.

The Examiner has not demonstrated that any of claims 1, 3, 21, 23, or 24 fails to particularly point out or distinctly claim "the subject matter which the applicant regards as his invention". Accordingly, the Examiner has failed to state a sustainable rejection under the second paragraph of 35 U.S.C. §112.

Claims 1, 3, and 21 were rejected under 35 U.S.C. §101 as lacking utility. Office Action, pages 2-3. It is noted that in

spite of his citation of judicial precedent in connection with other rejections made in the outstanding Office Action, the Examiner has not cited any decisions supporting this ground of rejection. Applicants respectfully submit that the process of reacting a chemical compound (A) as defined in the present claims with a chemical compound (B) as defined in the present claims to produce a chemical compound product of the reaction is "useful" within the meaning of the statute. Applicants had supplied references D1-D5 as evidencing the utility of the presently claimed process invention. The Examiner is apparently disregarding that evidence on the ground that it was not included in the specification. However, the disclosure of a patent application is directed to persons skilled in the art. The specification of a patent application need not - indeed, should not - provide information that is already within the expected skill of the art. Manifestly, the Examiner has failed to state a sustainable rejection under 35 U.S.C. §101.

Claims 1, 3, and 21 were rejected under the first paragraph of 35 U.S.C. §112, as fail to comply with the written description requirement. Office Action, pages 3-4. In his statement of this ground of rejection, the Examiner indicates that "Applicant must show possession of the invention by describing it with all the claimed limitations". Precisely which of the presently claimed limitations does the Examiner believe is not described in writing in the specification?

Claims 1, 3, and 21 were rejected under the first paragraph of 35 U.S.C. §112, as fail to comply with the enablement requirement. Office Action, pages 4-6. Regarding the enablement rejection, the Examiner argues that "The claimed process is not believable on its face". The Examiner is respectfully requested to clarify that statement.

In his analysis, the Examiner quite properly refers to the decision of the CAFC in *In re Wands*. However, the Examiner's analysis of the eight *Wands* factors is flawed.

Wands factors 1. & 2. - the breadth of the claims and the nature of the invention. The Examiner alleges that "the claimed invention involves a process of making any organic compound". Actually, the claimed invention involves a process for making only those organic compound that are addition or substitution reaction products of a compound (A) and a compound (B) or an oxidized product thereof. The reactant compounds (A) and (B) are defined in the claims.

Wands factor 3. - the state of the prior art. The Examiner argues that "There is no known prior art claiming a process for making all organic compounds". That may be true. In any case, however, the present claims certainly do not claim a process for making **all** organic compounds. Regarding the state of the prior art relevant to the presently claimed addition and substitution reactions, relevant background art is discussed on pages 2-6 of the specification. The

Examiner's attention is also directed to the Information Disclosure Statements filed herein.

Wands factor 4. - the level of ordinary skill in the art.

The Examiner indicates that

The level of ordinary skill in the art is limited to a process of making  $\alpha$ -hydroxy- $\gamma,\gamma$ -dimethyl- $\gamma$ -butyrolactone as disclosed in the specification.

Does this mean that the level of skill in the art is not high for the presently claimed processes of making other compounds such as  $\alpha$ -hydroxy- $\gamma$ -butyrolactone and  $\alpha$ -hydroxy- $\gamma$ -ethyl- $\gamma$ -propyl- $\gamma$ -butyrolactone? The Examiner is respectfully requested to explain what he means by his statement with respect to level of ordinary skill in the art.

Wands factors 5. & 6. - the level of predictability in the art and the amount of direction and guidance provided b the inventor. The Examiner alleges that the level of "predictability is very low and ... the amount of direction and guidance provided by applicant is limited to a process of making  $\alpha$ -hydroxy- $\gamma,\gamma$ -dimethyl- $\gamma$ -butyrolactone comprising the reaction of 2-propanol with ethyl acrylate in the presence of N-hydroxyphthalimide". The Examiner fails to indicate how he decided that the level of predictability is "very low". The present claims define the two classes of reactants that are being reacted with one another functionally as well as with reference to their structural components, as follows:

(A) a compound capable of forming a stable radical and being selected from (A1) oxygen-atom-containing compounds each having a carbon-hydrogen bond at the adjacent position to an oxygen atom, (A2) carbonyl-

group-containing compounds, and (A3) compounds each having a hydrocarbon group with a methine carbon atom

and

(B) a radical scavenging compound selected from (B1) unsaturated compounds, (B2) compounds each having a hydrocarbon group with a methine carbon atom, and (B3) heteroatom-containing compounds.

Accordingly, a high degree of predictability is inherent in the present invention. As for direction and guidance, the Examiner's attention is directed to **pages 24-107** of the specification, which provide **voluminous and detailed direction and guidance** as to how to practice the presently claimed invention.

Wands factor 7. - existence of working examples. The Examiner does not address Wands factor 7, the existence of working examples. The present specification includes thirty-eight **(38) different fully documented working Examples (!)** illustrating the practice of a wide variety of embodiments of the present invention.

Wands factor 8. - the quantity of experimentation needed to make or use the invention based on the content of the disclosure. It is not any experimentation, but only "undue" experimentation, that is forbidden by the statute. The Examiner has the burden of establishing - not simply arguing - that undue experimentation would be necessary. In any case, the present invention does not lend itself to "undue experimentation" problems. To establish coverage under claims 1, 3, and 21, one simply allows a compound capable of

forming a stable radical as defined in (A1)-(A3) to react with a radical scavenging compound as defined in (B1)-(B3) - in the presence of an imide compound of Formula (1) and, for claim 21, in the presence of a metallic co-catalyst - and then one determines whether an addition or substitution reaction product has formed. Where is the *undue* experimentation in this simple test? The Examiner is respectfully reminded of the facts of the *Wands* case and the conclusions of the Court in that case. In *Wands*, the success rate of the screening experiments was such that only 2.8% of the input hybridomas produced a useful antibody. In some of the screens, no useful hybridomas were identified. The *Wands* panel concluded that, despite this low success rate, the invention was enabled. Do to the nature of the present invention, the "screening" described above would presumably have a success rate close to 100%.

Applicants respectfully contend that all of the claims presented in this application are fully enabled by the disclosure.

In the paragraph bridging pages 5-6 of the Office Action, the Examiner alleges that the above arguments "have been fully considered". Unfortunately however the Examiner fails to indicate in the Office Action why each of those arguments is not persuasive.

In the paragraph bridging pages 5-6 of the Office Action, the Examiner refers to Table R3 and indicates that "by adding the table to the specification and applicable structures to the claims the

rejection would be overcome". Inasmuch as Table R3 is merely a compendium of the thirty-eight (38) working Examples herein, it has been, in effect, added to the specification. Does this remark by the Examiner mean to imply that only claims limited to the thirty-eight (38) working Examples can possibly be found to be enabled?

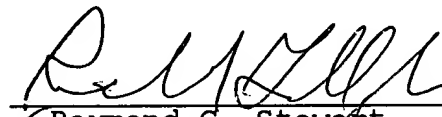
It is manifest that the Examiner has failed to satisfy his burden of proof with respect to the establishment of a sustainable rejection based upon failure to satisfy the enablement requirement of the first paragraph of 35 U.S.C. §112.

Please contact Richard Gallagher, Reg. No. 28,781, at (703) 205-8008 with any questions concerning this application.

If necessary, the Commissioner is hereby authorized to charge payment to Deposit Account No. 02-2448 any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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